

**“A COMPARITIVE STUDY OF OPEN SURGERY AND
RADIOFREQUENCY ABLATION FOR VARICOSE VEINS”**

Dissertation Submitted For

**M.S. DEGREE EXAMINATION
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KILPAUK MEDICAL COLLEGE
CHENNAI - 600 003**



**THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY
CHENNAI 6000032.**

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This is to certify that this dissertation titled “**A COMPARITIVE STUDY OF OPEN SURGERY AND RADIOFREQUENCY ABLATION FOR VARICOSE VEINS**” is bonafide record of work done by **DR G. KAVITHAL**, during the period of her post graduate study from May 2011 – April 2014 under guidance and supervision in the department of general surgery, Kilpauk medical college, Chennai, in partial fulfillment of the requirement for **M.S. General surgery** degree Examination of the Tamilnadu Dr MGR Medical University to be held in April 2014.

Prof. Dr. R. KANNAN, M.S. (Gen)
The Department Of General Surgery
Kilpauk Medical College
Chennai

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Prof. Dr. P. N. SHANMUGASUNDARAM, M.S. (Gen)
The Head of the Department Of General Surgery
Kilpauk Medical College
Chennai

ENDORSMENT BY HEAD OF THE INSTITUTION

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Prof. Dr. P. Ramakrishnan, M.D., D.L.O,
Dean
Kilpauk Medical College
Chennai

DECLARATION

I, DR.KAVITHAL hereby declare that this dissertation “**A COMPARITIVE STUDY OF OPEN SURGERY AND RADIOFREQUENCY ABLATION FOR VARICOSE VEINS**” is a bonafide, genuine research work done by me under the guidance of PROF. DR. KANNAN, PROFESSOR OF THE DEPARTMENT OF GENERAL SURGERY, KILPAUK MEDICAL COLLEGE, Chennai

Place: Chennai

Signature of the candidate

Date:

Dr. G. KAVITHAL

GUIDE:

PROF. DR. R.KANNAN, M.S.(GEN)
PROF OF GENERAL SURGERY
KILPAUK MEDICAL COLLEGE
CHENNAI

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ABBREVIATIONS

SFJ - sapheno femoral junction

SPJ - sapheno popliteal junction

CVI - chronic venous insufficiency

DVT - deep vein thrombosis

RFT - radio frequency ablation

EVLT - endo venous laser therapy

IL-1 - interleukin 1

VRT - vein recovery time

TIPP - trans illuminated power phlebectomy

TNF - tumor necrosis factor

TGF - transforming growth factor

AVP - ambulatory venous pressure

FDA - food and drug association

“A COMPARITIVE STUDY OF OPEN SURGERY AND RADIOFREQUENCY ABLATION FOR VARICOSE VEINS”

Abstract:

The treatment of choice in the new era for superficial and perforator venous reflux is Radiofrequency ablation (RFA). Obliteration of superficial venous system in short term follow up is similar for both RFA & venous stripping. Clinical improvement as measured by CEAP and venous severity score are similar in both groups. But RFA is less morbid than surgery. Patients who are undergoing RFA, return to work earlier than patients who underwent surgery.

Keywords:

Sapheno femoral junction, Long saphenous vein, Radio frequency ablation, Sapheno Popliteal vein, Chronic venous insufficiency, Ambulatory venous pressure.

AIMS & OBJECTIVES:

1. To access the obliteration of the superficial venous systems following conventional surgery and RFA at the end of three months.
2. To compare the clinical outcome between the surgery and RFA at the end of three months.

3. To compare the cost and the clinical stay among the surgery and RFA.

CONCLUSION

The favoured alternative choice in the treatment of superficial and perforator venous reflux disease in the newer era is the endovenous radio frequency ablation. The RFA not only out performs the traditional vein stripping and perforator interruption with regard to morbidity and outcome, it also reduces the formation of neovascularization that is frequently blamed reason for the higher recurrence rates seen with vein stripping.

Introduction:

The problem of varicose veins is one of the many prices man has to pay for gaining an erect posture, and so has been there since pre historic times. Till now no cure has been found though the surgery is the gold standard, balancing cosmetically acceptable result with a low incidence of recurrence and complications. It has always been a challenge. The expansion of minimally invasive techniques has made the treatment of superficial venous reflux and varicose veins, a rapidly evolving field!

Radio frequency ablation(RFA), transilluminated power phlebectomy(TIPP), Foam sclerotherapy, Endovenous laser therapy(EVLT), are newer minimally invasive techniques in the varicose veins treatment. Out of these techniques RFA have been mostly accepted by the patients all over the world. It is less invasive and need for post operative stay and pain are less as compared to conventional surgery. So a study has been made to compare the efficacy of the surgery and the RFA.

AIMS & OBJECTIVES:

1. To assess the obliteration of the superficial venous systems following conventional surgery and RFA at the end of three months.
2. To compare the clinical outcome between the surgery and RFA at the end of three months.
3. To compare the cost and the clinical stay among the surgery and RFA.

Review of Literature:

Varicose veins is the most commonest problem that causes significant morbidity in the lower limbs and thus leads to increased health care cost.

SYMPTOMS ; local discomfort like pain, itching, aching, burning discomfort,

Generalized symptoms like swelling, restless leg syndrome and heaviness and postural cramps are the commonly reported symptoms along with complaints about cosmetic appearance.

Due to hormonal influence, women are more prone. Night cramps and edema are the most common reported symptoms. There will not be any correlation between symptoms of the disease and the extent of the disease on examination.

The gold standard treatment of varicose veins is surgery, but recently many minimally invasive methods with equally good results have been used. Of all these newer methods, the most accepted is radio frequency ablation of the varicose veins.

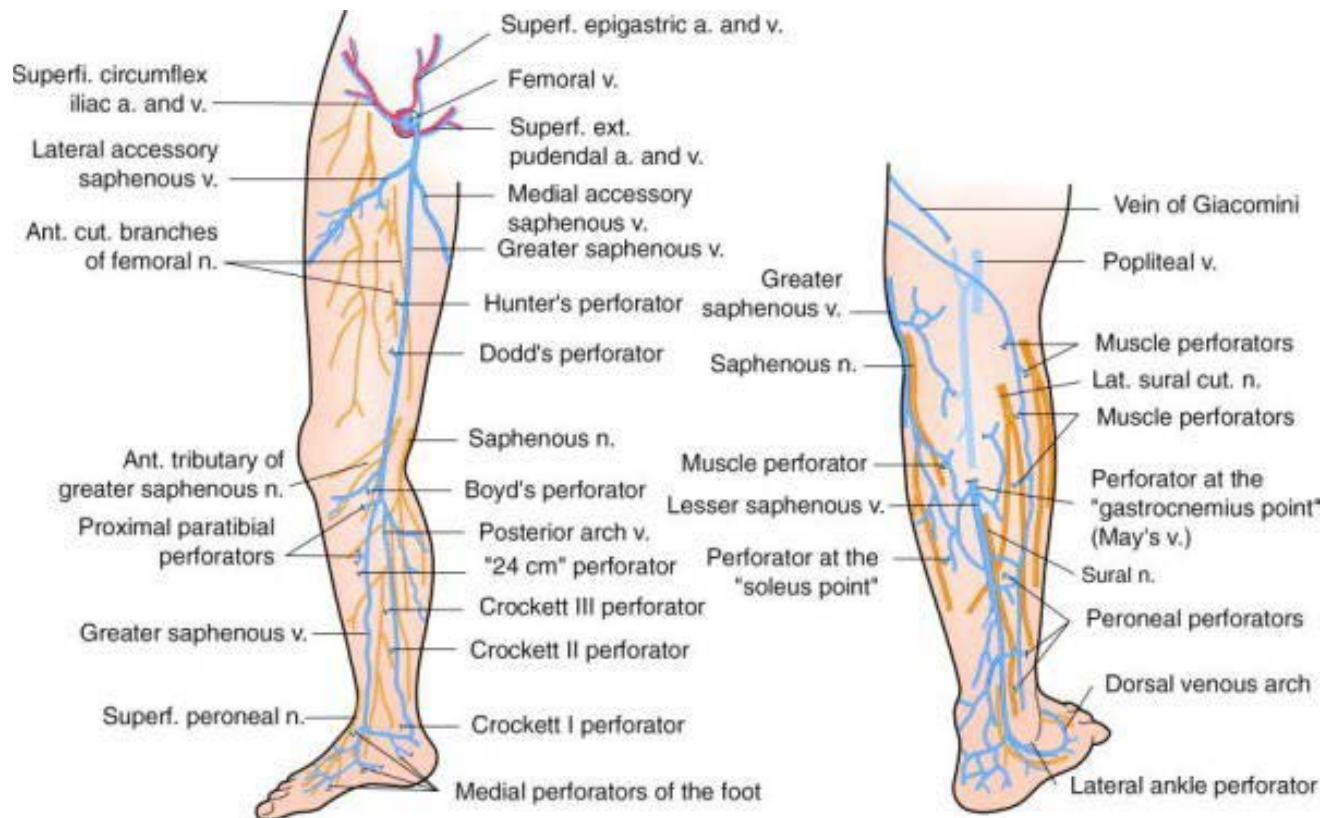
CHRONIC VENOUS INSUFFICIENCY

EPIDEMIOLOGY:

VARICOSE VEINS are comparatively common in females than males due to hormonal influence. It is difficult to define varicose veins as it has varied presentations. Minor venous abnormalities like thread veins are seen up to 40 -50 % of men and 50 -55% of women.

There will not be any correlation between the extent of the disease and the symptoms of presentation. Most of the lower limb symptoms have a non venous cause for their symptoms even if they have a main stem varicose disease.

Normal venous anatomy



The Great Saphenous Vein (GSV) runs from the medial side of the ankle and runs along the medial border of leg to join the femoral vein at the sapheno femoral junction. The short saphenous vein runs from the ankle along the lateral border of the leg to reach the saphenopopliteal junction (SPJ). Lateral accessory saphenous, posterior arch, vein of GIACOMMINI and other superficial veins can develop a pathology leading to chronic venous insufficiency

The venous system of the lower limbs are divided into superficial and deep systems and both are connected by the perforator veins. The superficial venous system is present above the musculo fascial layer and it has several truncal superficial veins and the inter connecting network of veins serving as a primary collecting system functioning as conduits and returning blood to deep venous system.

. The location of deep venous system is below the muscular fascia and becomes the collecting veins and the final outflow from the extremity and it is the . The axial vein follow the course of the named arteries and the inter muscular veins. The limb muscles and the venous sinusoids forms the intermuscular venous plexi.

The two calf veins merged to form the popliteal veins. On passing through the adductor canal, the popliteal vein becomes the femoral superficial vein . The superficial vein is joined by the deep femoral ,that is profunda femoris in the upper thigh region to form the common femoral vein which then becomes the external iliac vein.

The deep system is connected to superficial veins by various number of perforators in the leg and the thigh passing through the anatomical fascial spaces.

The perforators have bicuspid valves that are located throughout the deep and superficial veins that ensures that blood moves in only cephaloid direction, preventing its backflow.

The first perforator is usually located in the common femoral vein are less commonly in the external iliac vein. To overcome the effects of gravity the number of venous valves increases from proximal to distal leg, to prevent the increase the pressure within the distal veins,. The valves are oneway ie it prevents reflux of blood from deep to superficial veins.

The function of valves with venous muscle pumps allows the return of blood against gravity to the heart. The muscle pumps contraction, mainly in the calf along the foot and the thigh forces blood out of the venous plexus and up to the deep venous systems because of increased pressure that is developed within the facial compartments. Reflux is prevented by the valves.

The pressure within the veins is normally low, immediately after normal ambulation (15 -30 mm of Hg) as the system has been emptied by the muscle pump. Then the muscle pump relaxes allowing blood to return to the deep venous system via arterial inflow through the superficial and distal venous systems. With long period of standing the veins slowly fill and become distended, opening the

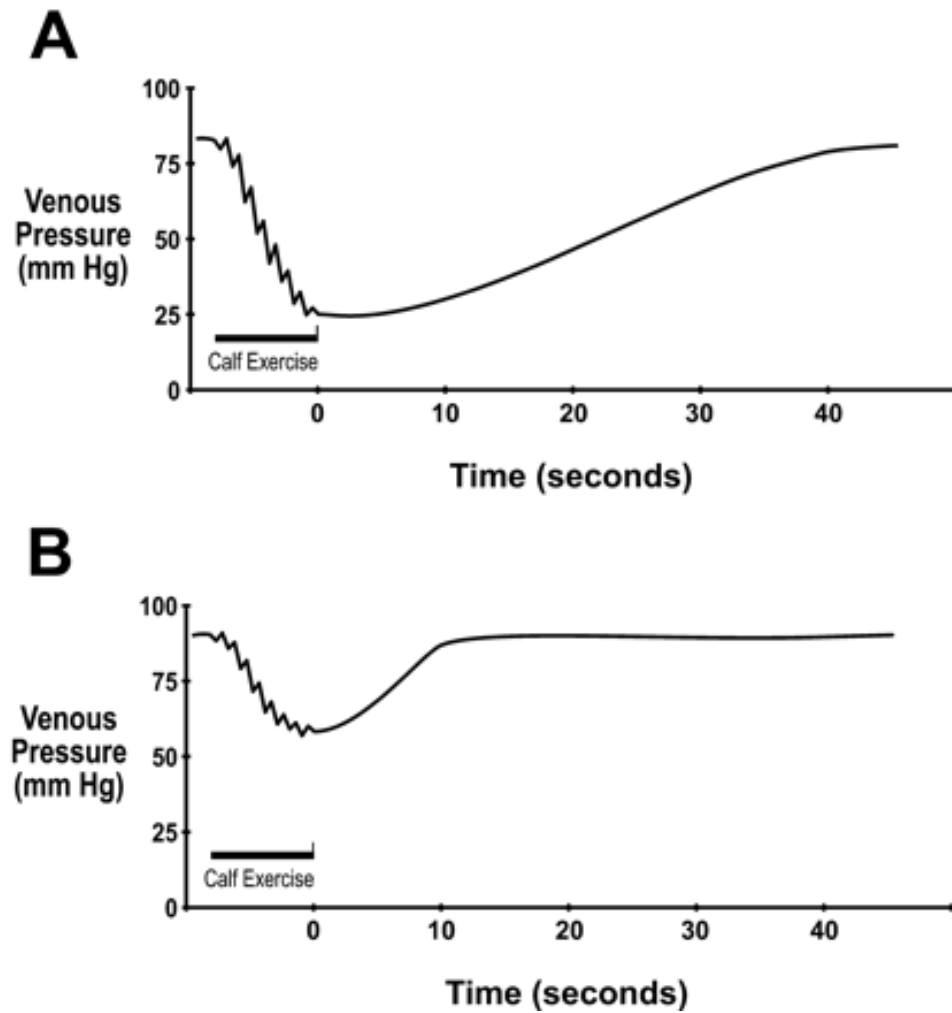
valves and eventually increasing the pressure. With contraction of muscle pump, the veins again empty and reduce the venous pressure.

Pathophysiology:

Macrocirculation:

The venous obstruction, venous reflux, calf muscle pump dysfunction or combination of these, are the cause for the signs and symptoms of chronic venous insufficiency. Reflux is the principle cause in most cases. CVI may be primary or secondary. The primary has no obvious etiological mechanism of valvular dysfunction, develops from the loss of elasticity in the vein valve. Secondary is due to valvular incompetence and there is an obvious antecedent event, most frequently a deep vein thrombosis.

Venous hypertension is caused by ambulatory venous pressure (AVP). AVP below 40 mm of Hg, patients have minimal incidence of venous obstruction. Venous recovery time (VRT) has also been used as the indicator of valve dysfunction.



The graph shows the measurement of AVP.

A – Normal venous pressure, resting venous pressure is approximately 80 -90 mm of Hg. With calf exercise drop in AVP is to 20 -30 mm of Hg, or > 50% decrease.

Refill takes more than or equal to 20 Seconds.

B - Abnormal venous pressure with deep venous reflux. Drop in pressure with exercise is < 50%, because of short refill time (less than 20 sec), return in venous pressure to resting levels is rapid.

MICRO CIRCULATION

There are many theories regarding the pathogenesis of venous ulcer. The oldest theories are venous stasis (Holmans 18in 1917) and arteriovenous shunts (Pratt19in1949, and Brewer20in1950). Homans suggested that hypoxia secondary to bloodstasis was responsible for ulceration. Subsequent studies did not show hypoxia in the limb with ulcer.^{21,22} The theory of arteriovenous shunts was strongly contested by findings of Lindemayr *et al.*, who used radioactive microspheres and could not demonstrate shunts in patients with ulcer.²³

The more recent theories have associated CVI with microcirculatory abnormalities, with the generation of an inflammatory response. In 1982, Browse and Burnand suggested that venous hypertension in the calf muscular pump system is transmitted through the perforating/communicating system to the superficial veins of the skin and the subcutaneous tissue of the calf.²⁴

This increase in pressure would distend the local capillary bed and widen the endothelial pores, allowing large molecules, mainly fibrinogen, to

escape into the interstitial fluid. Insoluble fibrin complexes form due to an inappropriate fibrinolytic activity in blood and interstitial fluid. Fibrin deposited around the capillary forms a barrier to oxygen and other nutrients, promoting cell death and ulceration (Fig. 1).

However, Falanga and Eaglstein, in 1993, could not demonstrate that the fibrin cuffs were a real barrier to diffusion, observing that they were discontinuous around the capillaries and that the venous ulcers healed despite their presence on the ulcer border.²⁵

In 1988, Coleridge Smith *et al.* proposed an alternative hypothesis to better explain venous ulcer pathogenesis.²⁶ According to these authors, increased pressure in the venous system, in the orthostatic position, leads to a pressure decrease of capillary perfusion, reducing the capillary flux sufficiently to cause leukocyte trap.

The trapped leukocytes release toxic metabolites of oxygen and proteolytic enzymes which then cause capillary damage, making capillaries more permeable to large molecules and promoting additional leukocyte trap. The permeability increase could result in extravasation of fibrinogen and other plasma proteins which would cause fibrin cuff formation. The trapped leukocytes would

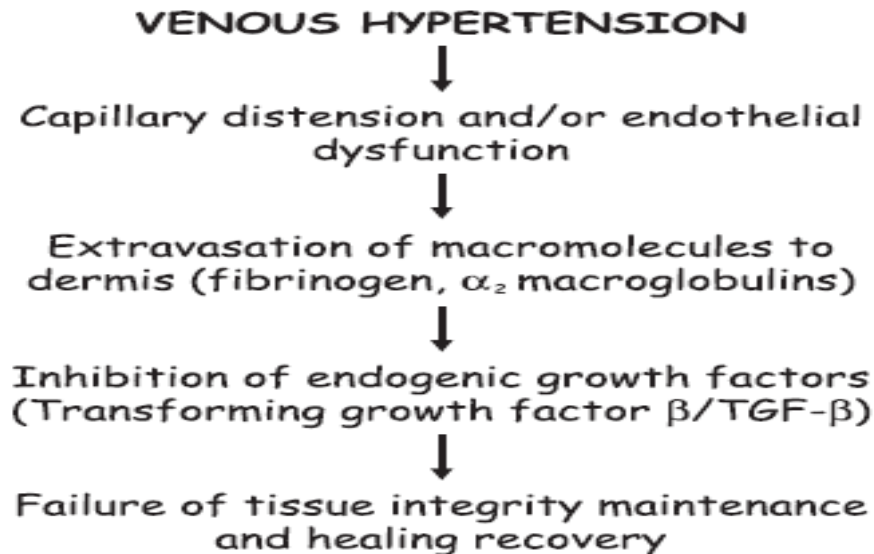
additionally damage the circulation of the affected capillaries, resulting in ischemic areas around the capillary loop (Fig. 3).

This theory has been criticized because the studies were performed with patients whose cutaneous alterations were secondary to chronic venous hypertension. Therefore it is difficult to determine whether the leukocyte trap was causing the local inflammatory process or was secondary to it.

In 1991, Claudy *et al* . proposed that activation of leukocytes released free radicals and proteolytic enzymes, and increased elastase activity, causing epithelial injury and increased vessel permeability, resulting in deposition of pericapillaryfibrin.²⁷ Furthermore, these leukocytes would release tumor necrosis factor alpha(TNF- α), which decreases fibrinolytic activity, and secondarily induces the formation of pericapillary fibrin cuffs. Both fibrin and toxic metabolites released by leukocytes can explain the difficulties encountered in ulcer healing.

In 1993, Falanga *et al* . proposed that capillary distension or injury of endothelial cells due to venous hypertension leads to extravasation of fibrinogens, α 2-macroglobulins and other macromolecules, from veins to dermis.²⁵ These Macro molecules can cause a functional inhibition of endogenous growth factors, for instance transforming growth factor $-\beta$ (TGF- β), making them unable to maintain tissue integrity and healing recovery (Fig. 3).

Fig 3. Falanga and Eaglesteins theory

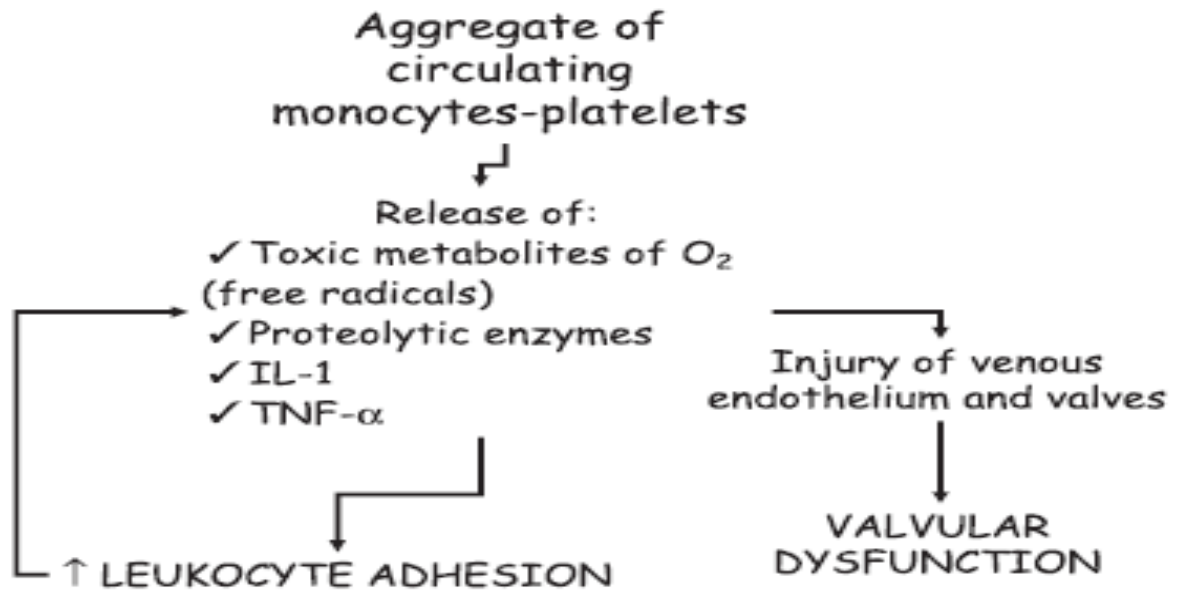


There is evidence supporting this hypothesis. For example, there are growth factors abundantly present in venous ulcer, and some fluid collected from venous ulcers causes *in vitro* inhibition of proliferation of some types of important healing cells, including fibroblasts, endothelial cells and keratinocytes.^{28,29} Therefore, the micro environment of venous ulcer is negative for these growth factors and makes healing difficult. The notion that venous ulcers contain a functional trap for growth factors would provide an explanation for unsuccessful single growth factor therapy, but it is difficult to explain how these events would cause inflammation and tissue death.

The role of activated leukocytes in venous ulcer development has been studied. Monocytes are likely the leukocytes involved in many clinical stages in the development of CVI.³⁰ Besides activated monocytes, aggregates of monocytes–platelets have been recently implicated in CVI and venous ulcer etiopathogenesis. Peyton *et al* . were the first to show an increased number of these aggregates in patients with venous ulcer.³¹ In 1999, Powell *et al* . showed an association of all classes of CVI with the increase of these circulating aggregate levels.³² They also suggested that the circulating aggregate of monocytes–platelets would be able to injure the venous endothelium and valves, leading to the development of valvular dysfunction.

The activated leukocytes release the substances mentioned above and the activated platelets release interleukin-1 (IL-1) and TNF- α , and both would act in endothelial cells to increase leukocyte adhesion (Fig. 4). However, the stimuli that activate monocytes and platelets are still unknown, as are the roles of these circulating aggregates. Activated monocytes as a cause of CVI are still the subject of investigation.

Fig4.Scheme for powell et al.



In vivo microscopy studies have revealed areas of capillary microthrombosis in lipodermatosclerotic skin³³ and reductions in capillary numbers in areas of prior ulceration (atrophie blanche).³⁴ This suggests that cutaneous nutrient circulation may contribute to venous ulceration and recurrence. Despite the many studies that have been carried out and the various hypotheses that have been proposed, the real mechanism of CVI development and venous ulcer is still unknown. It is possible that each mechanism described above is important in some cases. Therefore, the etiopathogenesis of these diseases is still the subject of many current studies.

Risk factors:

Heredity plays a significant role in the development of varicose veins. Moderate venous disease is independently related to age, previous hernia surgery, and normotension in both sexes. In men, current walking, the absence of cardiovascular disease, and not moving after sitting are also predictive. Additional predictors in women are weight, number of births, oophorectomy, flat feet, and not sitting. For severe disease, age, family history of venous disease, waist circumference, and flat feet are predictive in both sexes. In men, occupation as a labourer, cigarette smoking, and normotension are also independently associated with severe venous disease. Additional significant and independent predictors in women are hours standing, history of leg injury, number of births, and cardiovascular disease, but African American ethnicity is protective.

The C-E-A-P classification of varicose veins

The recent scoring system that stratifies venous disease based on *clinical* presentation, *etiology*, *anatomy*, and *pathophysiology*. This classification scheme is useful in helping the physician coherently and thoughtfully assess a limb afflicted with venous insufficiency and then arrive at an appropriate treatment plan.

CEAP Classification of Chronic Lower Extremity Venous Disease:

C	The Clinical signs (grade 0–6, supplemented by “A” for asymptomatic and “S” for symptomatic presentation)
A	The Anatomic distribution (<i>superficial</i> , <i>deep</i> , or <i>perforator</i> , alone or in combination)
E	The Etiologic classification (<i>congenital</i> , <i>primary</i> , <i>secondary</i>)
P	The Pathophysiologic dysfunction (<i>reflux</i> or <i>obstruction</i> , alone or in combination)

CLINICAL CLASSIFICATION (C0–6):

Any limb with possible chronic venous disease is first placed into one of seven clinical classes (C0–6) according to the objective signs of disease.

Clinical Classification of Chronic Venous Disease:

Class 0	There are No visible or palpable signs of venous disease.
Class 1	Presence of Telangiectasia, reticular veins, malleolar flare.
Class 2	Varicose veins.
Class 3	Presence of Edema without skin changes.
Class 4	Skin changes ascribed to venous disease (e.g., pigmentation, venous eczema, lipodermatosclerosis)
Class 5	Presence of Skin changes as defined above with healed ulceration
Class 6	Presence of Skin changes as defined above with active ulceration

As the Limbs in higher categories have more severe signs of chronic venous disease and may have some or all of the findings defining a less severe clinical category, Each limb is further characterized as asymptomatic (A), for example, C0–6,A, or symptomatic (S), for example, C0–6,S. Symptoms that may be associated with telangiectatic, reticular, or varicose veins include lower extremity aching, pain, and skin irritation. Treatment may alter the clinical category of

chronic venous disease. Limbs should therefore be reclassified after any form of medical or surgical treatment.

ETIOLOGIC CLASSIFICATION (EC, EP, or ES)

The etiology of Venous dysfunction may be congenital, primary, or secondary. Congenital venous disorders are present at birth but may not be recognized until later. The method of diagnosis of congenital abnormalities must be described. The Primary venous dysfunction is defined as venous dysfunction of unknown cause but not of congenital origin. The Secondary venous dysfunction denotes an acquired condition resulting in chronic venous disease, for example, deep venous thrombosis.

Etiologic Classification of Chronic Lower Extremity Venous

Disease:

Congenital(EC)	Cause of the chronic venous disease present since birth.
Primary (EP)	Chronic venous disease of undetermined cause

THE ANATOMIC CLASSIFICATION (AS, AD, or AP):

Anatomic site(s) of the venous disease should be described as superficial (AS), deep (AD), or perforating (AP) vein(s). Any of these systems may be involved in any combination. For the reports requiring greater detail, the involvement of the superficial, deep, and perforating veins may be localized by use of the anatomic segments.

Segmental Localization of Chronic Lower Extremity Venous Disease

Superficial Veins (AS1–5)

Segment No.	Vein(s) involved
1	Telangiectasia/reticular veins Greater (long) saphenous vein
2	<i>Above the knee</i>
3	<i>Below the knee</i>
4	Lesser (short) saphenous vein
5	Non saphenous origin

Deep Veins (AD6–16)

Segment No	Vein(s)
6	The Inferior vena cava
Iliac	
7	<i>Common iliac</i>
8	<i>Internal iliac</i>
9	<i>External iliac</i>
10	Pelvic: gonadal, broad ligament
Femoral	
11	<i>Common femoral</i>
12	<i>Deep femoral</i>
13	<i>Superficial femoral</i>
14	Popliteal vein
15	Tibial (anterior, posterior, or peroneal)
16	Muscular (gastrointestinal, soleal, other)
Perforating Veins (AP17,18)	

17	Thigh perforators
18	Calf perforators

PATHOPHYSIOLOGIC CLASSIFICATION (PR, O)

Clinical signs or symptoms of chronic venous disease result from reflux (Pr), obstruction (Po), or both (Pr,o).

Pathophysiologic Classification of Chronic Lower Extremity Venous Disease

Reflux (PR)

Obstruction (PO)

Reflux and obstruction (PR,O)

Clinical features:

The patient with symptomatic varicose veins relates, most often, symptoms of aching, heaviness, discomfort, and sometimes outright pain in the calf of the affected limb. Many causes of leg pain are possible, and most may coexist.

Therefore, defining the precise symptoms of venostasis is necessary.

These symptoms may be of gradual onset or may be initiated by a lancinating pain, and they may precede the clinical appearance of the varicosity. Discomfort

usually occurs during warm temperatures and after prolonged standing. Varicose vein symptoms are often disproportionate to the degree of pathologic change. Patients with small, early varices may complain more than those with large, chronic varicosities. The initial symptoms may vary from a pulsating pressure or burning sensation to a feeling of heaviness. The pain is characteristically dull, does not occur during recumbency or early in the morning, and is exacerbated in the afternoon, especially after long standing. This is particularly worse at the end of the day, most likely due to prolonged sitting or standing that results in venous distention and associated pain. The discomforts of aching, heaviness, fatigue, or burning pain are relieved by recumbency, leg elevation, or elastic support. In the case of women, the symptoms are often most troubling and exacerbated during the menstrual period, particularly during the first day or two. It is not unusual for a patient to have significant reflux at the saphenofemoral junction and yet not have impressive varicose veins on physical examination.

Additionally, the patient may have combined superficial and deep venous insufficiency, and thus a clear diagnosis, with the aid of the CEAP system, is useful in determining treatment. Primary varicose veins consist of elongated, tortuous, superficial veins that are protuberant and contain incompetent valves. These produce the symptoms of mild

swelling, heaviness, and easy fatigability. Primary varicose veins merge imperceptibly into more severe CVI. Swelling is moderate to severe, an increased sensation of heaviness occurs with larger varicosities, and early skin changes of mild pigmentation and subcutaneous induration appear. When CVI becomes severe, marked swelling and calf pain occur after standing, sitting, or walking. Multiple dilated veins are seen associated with various clusters and heavy medial and lateral supramalleolar pigmentation.

Cutaneous itching is also a sign of venostasis and is often the hallmark of inadequate external support. It is a manifestation of local congestion and may precede the onset of dermatitis. This, and nearly all the symptoms of stasis disease, can be explained by the irritation of superficial nerve fibers by local pressure or accumulation of metabolic end products with a consequent pH shift.

External hemorrhage may occur as superficial veins press on overlying skin within this protective envelope.

Complications:

Chronic venous insufficiency can lead to hyperpigmentation, lipodermatosclerosis and superficial thrombophlebitis. There is an increased risk of cellulitis, leg ulceration, and delayed wound healing. Long-standing CVI also may

lead to the development of lymphedema. Long standing ulcers can give rise to Marjolin's ulcer (squamous cell carcinoma).

Evaluation: DIAGNOSTIC WORK UP

The preoperative evaluation requires the differentiation between primary and secondary varicose veins and to evaluate the patency of deep venous system. Patient was examined in supine and standing.

CLINICAL EXAMINATION

1. BRODIE TRENDLENBURG TEST:

To determine the in competency of the sapheno-femoral and communicating system. Test consists of two parts.

A) The patient is placed in supine position and leg is raised to empty the veins. The sapheno-femoral junction is compressed with thumb and the patient is asked to stand quickly with thumb released quickly. If the sapheno-femoral valve is incompetent the varices will be filled quickly.

B) In this test after emptying the veins with occluding the SF junction. Patient is asked to stand pressure is NOT released. If the perforator is incompetent varices will be filled slowly.

2. TORNQUET TEST: (OSHNER MAHONER TEST)

Superficial veins are emptied and tourniquets are tied around the thigh and leg at different levels. Patient is now asked to stand up. A vein filled above or below a tourniquet represents the presence of an incompetent vein. By altering the tourniquet down insteps, position of the incompetent perforator can be identified.

3. PERTHE'S TEST

Veins are emptied and elastic bandage is applied to the lower limb. Patient is asked to move around and exercise. Severe crampy pain occurs in DVT.

4. MODIFIED PERTHE'S TEST

Tying a tourniquet in thigh so as to prevent the reflux .if the deep vein and the perforators are normal the varicose vein will shrink. If blocked, they will become more distended.

5. SCHWARTZ TEST

In long standing case, if a tap is made on the lower part of the leg. Impulse can be felt at the saphenous opening with the other hand.

6. PRATT TEST

Tying an elastic bandage empties veins; tourniquet is applied at the groin. Bandage is now removed & applied from groin downwards. At the site of perforators blow out can be seen and marked.

7. COUGH IMPULSE TEST: (MORISSEY'S)

Veins are emptied, on coughing an impulse is felt in the long saphenous vein if sapheno-femoral valve is incompetent. A bruit may be heard on auscultation.

8. FEGAN'S TEST

In standing posture, places of excessive bulge were marked. Veins are emptied in recumbent position. At the marked site gaps are pits may be felt in the deep fascia, which transmits the imperforate vein.

TEST FOR DVT:

9. HOMAN'S SIGN

Forceful dorsiflexion of the foot with knee extended will elicit pain in calf.

10. MOSSES SIGN

Squeezing the calf from side to side causes pain in the thrombosed deep vein.

ABDOMINAL EXAMINATION

To look for secondary causes.

PERIPHERAL PERFUSION ASSESSMENT

INVESTIGATIONS

NON INVASIVE

A) BIDIRECTIONAL DOPPLER VELOCITY STUDY

10MHz and 5 MHz are suitable for superficial and deep venous systems.

Audible signals and their directions are observed in rest, abdominal compression, during Valsalva maneuver, thigh and calf compression.

Superficial venous insufficiency can differentiate from deep vein insufficiency by

comparing saphenous and posterior tibial vessel at the supra malleolar level.

uperficial venous insufficiency is defined as abnormal reflux in saphenous vein

alone. In deep vein insufficiency there is reflux in both the veins. Incompetent communicating or valves are detected by auscultation with Valsalva maneuver or augmentation there is abnormal reflex towards probe.

Retrograde flow detected by bi-directional probe detects the valvular incompetence. When there is absence of spontaneous flow or diminished augmentation by distal compression indicates obstruction.

B) DUPLEX IMAGING / COLOUR FLOW IMAGING

Duplex imaging permits examination of the short and long saphenous veins as well as the perforating veins in the superficial system. Femoral, popliteal, and calf veins are the deep veins imaged.

Saphenofemoral competence, saphenous vein diameter, wall thickness, diameter of the saphenous tributaries, status of perforators, valvular competence within the saphenous vein & patency of the deep veins should be assessed. Valvular Competency is assessed by three phenomenon. A) Direction of blood. B) Valve thickness. C) Valve cooption.

INDICATIONS:

1. To R/O deep vein thrombosis

2. To R/O anatomical variation of the superficial system
3. Short saphenous varicosities
4. 4.Recurrent varicosities

LIMITATIONS

1. Operator dependent.
2. Takes long time.

C) PHOTO PLETHYSMOGRAPHY

Used to demonstrate an “abnormal brief recovery time” after exercise, is restored to normal when the suspected pathway of incompetence is selectively occluded by finger. An unequivocal response is accepted as an evidence of incompetence.

D) AMBULATORY VENOUS PRESSURE:

It is defined as superficial venous pressure in the ankle in standing position after 10 tip toe movements. Patient stands motionless by holding the frame. Superficial venous pressure measured by cannulating dorsal venous arch, is usually 90 mmhg and it depends upon the height of the individual.

Then the patient performs 10 tiptoe movements, the pressure usually falls to 15-30 mm Hg. Once again patient stands still. Venous pressure again falls to base line. Time taken to regain 90% of the baseline level is called Refill Time 90. This is usually 18-40 seconds. This is a functional test, which assess the efficiency of the venous systems.

INVASIVE:

ASCENDING PHLEBOGRAM

It's the 'gold standard investigation' for demonstrating venous occlusion and pattern of collateral flow. It is only used when Doppler can't clearly exclude deep vein occlusion.

INDICATIONS:

1. To demonstrate deep vein thrombosis of calf, pelvic varicose veins and IVC.
2. Investigate secondary and recurrent varicose vein.
3. Suspicion of venous malformation.

In presence of varicose veins the appearance of the deep veins before and after the exercise is same as normal veins but superficial vein may be visualized when it is associated with perforator incompetence.

They show dilation and become tortuous following DVT. When obstructed numerous valveless collaterals can be visualized. Following exercise there is poor emptying of the dye from the deep veins, increased filling of the collaterals, perforators and superficial veins. Clots will be seen as filling defects and if recanalised will have irregular margins.

Radiographic signs of DVT are abrupt termination of contrast medium above or below the obstruction, Nonfilling of the entire system, diversion of the flow through the collaterals.

FALSE POSITIVE – Turbulence around the valves, arterial impaction, mixing defects, entry of non-opacified blood, air bubble and overlying band. Multiple planes and films, Valsalva maneuver, large dose contrast, semi-erect position helps in reducing false positive results.

RADIO NUCLEIDE PHLEBOGRAPHY:

Injection of technetium 99m free or albumin labeled the superficial vein and applying compression and diverting the contrast predominately into the deep veins thrombosis can be identified.

- ❖ Delayed appearance time.
- ❖ Dilution or absence of portion of normal course of major venous segment.

- ❖ Presence of collateral pathway.
- ❖ Delay in disappearance of radio-nucleide (hot spots).
- ❖ Abnormal dilution effect associated with excessive collateral
- ❖ flow from venous segments that don't contain
radio-nucleide.
- ❖ Rate of passage of isotope is equal and rapid in both the
limbs. This doesn't occur in venous thrombosis.

VARIOUS MODALITIES OF TREATMENT

TREATMENT:

1. Conservative treatment.
2. Medical treatment.
3. Surgical treatment.

CONSERVATIVE TREATMENT:

- GRADED COMPRESSION STOCKINGS.
- UNNA BOOT
- MULTILAYER COMPRESSION DRESSINGS.
- BISGARD METHOD.
-

BISGARD'S METHOD:

- ❖ Massage in elevation of the whole limb particularly to soften the indurated area around the ulcer .
- ❖ Passive movement to maintain the mobility of the ankle and foot.
- ❖ Active movement to the calf in elevation and sitting (with compression bandage).
- ❖ Teaching correct method of walking placing heel down first and using the calf muscle to lift the heel back. Thus giving spring to the walk, therefore improving the venous pump.
- ❖ A firm elastic bandage is applied spirally from the base of the toe to the knee. So that movements in walking produces alternatively stretch and relax. Thus the bandage produces add on venous pumping effect.

COMPRESSION THERAPY:

Numerous mechanisms have been proposed to explain the benefits of compression therapy.

MACROVASCULAR:

- ❖ Decrease wall tension and thus further damage to elastin and collagen structure in the wall.
- ❖ Increase the velocity.
- ❖ Decrease the force of reflux in the perforators.
- ❖ Abolish the refluxing blood and thus reducing the venous load.
- ❖ Reduce edema and skin tension.
- ❖ Reduce AVP.
- ❖ Improve refill times.

MICROVASCULAR:

Return of starling forces, haemostasis, and leucocytes margination to normal.

- ❖ Prevents excessive fluid and protein filtration.
- ❖ Decreases pressure in post capillary venules.
- ❖ Augmenting lymphatic clearance.
- ❖ Augmenting release of prostacyclin and plasminogen activator from the endothelium.

Compression theory:

- Class-I <25 mmhg at ankle. Thromboembolic prophylaxis and early varicose veins.
- Class –II 25-35 mmhg. Advanced varicose veins, odema, early CVI.
- Class-III 35 –45 mmhg. Moderate to severe CVI.
- Class-IV >45 mmhg severe CVI and lymphodema.

MEDICAL TREATMENT:

1. PENTOXIPHYLLINE- Cytokine antagonist having some fibrinolytic activity.
2. CALCIUM DOBESILATE- Increases lymphatic flow with macrophage-mediated proteolysis, hence reducing edema.
3. DIOSMIN-Flavaniod RUTIN, which increases venous tone and improves lymphatic drainage and platelet microcirculation.
4. PROSTAGLINDIN -PGE1- Reduces WBC activation, platelet aggregation and vaso-dilation.
5. FREE RADICAL SCAVENGERS.
6. ACETYL SALICYLIC ACID- To reduce platelet adhesion.

7. ZINC- In venous ulcer there is decreased level of drugs.

Hence Zn supplementation promotes healing.

SCLEROTHERAPY

First described by MEPHECTERS, popularised by FEGAN (1963).

INDICATIONS:

1. Confined to below knee, which are not truncal veins.
2. Recurrent or residual veins
3. Telangiectasia
4. Patient not willing for surgery

CONTRAINDICATIONS:

DVT AND SF Incompetence

PRINCIPLE:

Sclerosant produces chemical phlebitis and on apposition produces obliteration of the lumen.

SCLEROSANTS:

3% Sodium tetra decyl sulphate, ethanolamineoleate, sodiummorruate polidocanol, hypertonic saline.

DISADVANTAGE:

Not suitable for large veins, allergic problems, extravasations may cause skin necrosis, local pain, periphebitis, intra arterial injection and rarely DVT.

PROCEDURE:

Patient sits in a waist height couch with lower limb horizontal. Needle with sclerosant is inserted into the skin marks, which are made previously. Vein is emptied by elevating the limb. Sclerosant is injected into the vein, which is compressed from above and below. As soon as the injection is over, the site is compressed with cotton ball. To prevent refilling of vein and compressive bandage is applied. Patient is encouraged to walk immediately. Bandage is applied for 3 weeks. Regular follow up and further injections may be needed for residual and recurrent varicosities.

SURGICAL MANAGEMENT:**INDICATIONS:**

Symptoms like aching, heaviness, edema , which are relived by compression therapy.

1. Chronic venous insufficiency.
2. Large varicosities subjected to trauma.
3. Cosmetic.

Preoperative marking is the most important step in surgical procedure.

SURGERIES FOR SUPERFICIAL VARICOSITIES:

- ❖ Simple high and flush ligation of sapheno-femoral or/and sapheno popliteal junction. (trendelenburg procedure)
- ❖ Ligation and stripping.
- ❖ Multiple phlebectomies by rivlin.
- ❖ Cockett and Todd's subfacial ligation of perforators.
- ❖ Linton's radical subfacial ligation of perforators
- ❖ Vohra and Odognon introduced endoscopic venous surgery.

Contraindications for surgery:

1. DVT.
2. Arterial ischemia.
3. Skin and soft tissue infection.
4. Lymphoedema.
5. Bleeding diathesis.
6. Pelvic tumor.
7. Poor anaesthetic risk.
8. Patient is on OCP is relative contraindication.

VENOUS RECONSTRUCTIVE SURGERY:

It is only when there is chronic obstruction and to correct the reflux.

OBSTRUCTION

DE-PALAMA

It is designed to bypass unilateral ILIAC VEIN OCCLUSION. Contra lateral LSV is tunneled suprapubically and anastomosed to patent common femoral or superficial femoral.

MAY HUSNI OPERATION

Obstructed femoral segment may be by-passed by anastomosing transected competent LSV to the side of popliteal vein.

REFLUX CORRECTION

The edge of the floppy wall cusps can be sutured to the vein wall.

KISTNER OPERATION

Involves longitudinal venotomy directly through commissure.

VALVULOPLASTY

It is of two types.

External- Vein diameter around the incompetent valve is reduced by vein wall plication and synthetic cuff around the vein.

Internal-Transverse incision above the level of the valve and commissural reefing is performed.

VEIN VALVE TRANSPLANTATION:

Autologous valve transposition interposes a segment of axillary or brachial vein, continuing a competent valve into an incompetent deep veins. Procedures using synthetic, mixed and animal valves are in experimental stage.

VEIN TRANSPOSITION:

An incompetent superficial vein can be transected and end to end or end to side to profundafemoris or long saphenous vein which has competent valve.

NEWER MODALITIES OF TREATMENT:

Endo-venous laser surgery

Endo-venous cryosurgery

COMPLICATION OF VARICOSE VEINS:

1. Odema.
2. Pigmentation.
3. Eczema.
4. Ankle flare.
5. Thrombophlebitis.
6. Varicose ulcer.

7. Haemorrhage.
8. Periostitis.
9. Calcification.
10. Equinus deformity.

CAUSES FOR RECURRENCE:

- ❖ Inaccurate pre op assessment.
- ❖ Incomplete operative technique.
- ❖ continuing same pattern of lifestyle.

Radio frequency ablation (RFA):

Endovenous RFA which is also VNUS CLOSURE PROCEDURE, is a catheter based endovascular intervention. Passing the RF energy into tissue to cause destruction is safer and more controllable than other methods. Mode of RF energy delivered in continuous or sinusoidal wave mode. There will not be stimulation of neuromuscular cells when a high frequency (200 – 3000 KHZ) is used. The mode by which RF current heats tissue is resistive heating of a narrow rim of tissue that is in direct contact with the electrode. The planes of Deeper tissue planes are then slowly heated by conduction from the small region of volume heating.

The RFA heat production is caused by the resistance of the tissue in vein walls allowing the passage of the current. The electrodes which is selectively insulated results in the preferential delivery of the RF energy to the vein wall and minimal heating of the blood within the vessels.

The thermal effect produced on the vein wall is directed related to the treatment temperature and treatment time. With the temperature needed at the range of ment of 85° -90°C at a pullback speed of 3 – 4 cm/min, the thermal effect induced sufficient collagen contraction to occlude the lumen, while limiting heat penetration.

Laser system is the other endovenous catheter based thrombo ablation technique . The method by which the laser heat is generated is by the action of laser on chromophore. The mechanism of damage to the vein wall is the generation of steam bubble around the laser tip.

RFA TECHNIQUE:

RFA is done by using the closure catheter. There are currently three types of catheter.

1. The Closer PLUS which is in both 6 Fr and 8 Fr for saphenous veins & accessory branch.
2. The Radio frequency system: Closure RFS and Closure PLEX catheters for perforator veins.
3. The newer released, Closure FAST catheter for saphenous veins and accessory branches.

The design of the closer PLUS catheter is for delivery of controlled RF to shrink vein wall collagen, and induces the collapsible catheter electrodes around which the vein will shrink, and there is a central lumen to allow a guide wire or for the fluid delivery structures, within a 5 Fr catheter. Thus the design permits treatment of veins as small as 2 mm and as large as 24mm.

The temperature is measured by the thermocouple on electrode and then provides feedback to the RF generator. The control unit displays The power, temperature, impedance, and elapsed time are displayed by the control unit so that precise temperature control is obtained. The generator of the RFA unit delivers the minimum power necessary to maintain the desired electrode temperature.

PROCEDURE:

The anesthesia which may be given is oral or intravenous sedation and put in a supine position on the adjustable table. The path of the great saphenous vein (GSV) that is from the saphenofemoral junction to the knee, and that of the lesser saphenous vein (LSV) from its junction with the gastrocnemius, and the popliteal or the other deep vein to mid calf and finally the accessory branch from its origin to the knee is mapped and marked with indelible ink. Nitro paste patch may be applied to help to dilate the vein and thus prevent venospasm.

Patient is painted and draped, the access sites and the sites marked already are infiltrated with 1% buffered xylocaine solution without epinephrine. The vein condition is accessed using the ultrasound guidance with 21 G needle. The needle and wire, which are smaller, much more important in causing venospasm than in the 18 G needle. With the use of the Seldinger technique, the introducer is passed in the vein. Then a 6 or 8 Fr catheter is passed upto the end point. The catheter is delivered 1 cm below the ostium of the superficial epigastric vein in the great saphenous vein. Then the position is confirmed by USG and the patient is placed into the significant trendelenburg position and about 200 – 400 ml of the

tumescent fluid (which contains Normal saline, 1% xylocaine with epinephrine, bicarbonate) is then injected directly. The use of tumescent is to provide local anaesthetic, to protect the surrounding tissues from the heat and compressing the vein around the catheter electrode and thus complete vein wall treatment will be obtained. To optimize exsanguination of the vein Circumferentially placed Esmarch wrap can be applied to optimize the exsanguination of the vein. The temperature: 85 to 95 deg C is maintained at tip of the catheter is 85 to 95 deg C.

The rate of withdrawal varies with desired treatment temperature. With the help of duplex examination, At conclusion of the procedure, the patency of the common femoral artery and then common femoral vein, successful contraction of the GSV, with residual diameter < 2mm and flow through the SFJ into the lateral epigastric vein are confirmed. The elastic wrap bandages are then placed for the patient and also asked to wear graduated compressed stockings with 30 mm Hg of compression and advised to walk at least for 30 min per day.

The patients are advised to start the normal activities immediately and encouraged to perform aerobic exercise but to avoid weight lifting for the

next 2 – 3 days. After 72 hours , A duplex ultrasound scan should be performed in the postoperative period to rule out any evidence of DVT.

The technique for performing perforator vein RFA requires more detailed mapping than that is required for superficial veins. This is Because they are not linear like the superficial and they are more curvilinear and angulated throughout their full course. When an adequate angle is found, and site of access is marked, a rigid radiofrequency stylet is used to access the perforator by using duplex ultrasound. Then the catheter is advanced to reach the level of muscular fascia and held in position, and tumescent fluid is infiltrated above and below the tip of the catheter. The treatment temperature ranges between 85 – 90° C for 5 min, pulling back 1-10 mm during the last 1 min. In the first 4 minutes, the catheter tip is rotated to the 12, 6, 3, 9 O'clock positions, each for 1 min.

Although the most common way is the SEPS recently to treat incompetent perforator veins, there are significant advances of using ultrasound guided endovenous RFA. Intervention here is truly minimally invasive and so that can be performed in the office. In SEPS, the approach is significantly limited by the perforating vein location. RFA procedure can also allows the flexibility of repeat treatment for persistent or newly

developed varicosities. The USFDA approved the VNUS closer system received in March 1999.

COMPLICATIONS:

DVT:

DVT is a significant risk in any surgery. It can be originated from the treated superficial or perforator veins and can also extent into deep venous system.

Paraesthesia:

It was reported to occur in 9 -19 % of limbs within one week of the procedure and it then gradually resolved over time. The superficial branch of the sural nerve and the paroneal nerve emerges around the midcalf level and should be avoided in the RFA treatment.

EFFICACY & OUTCOME:

Ambulation is encouraged within 72 hours of the procedure. At end of one week, 60% of veins were hypoechogenic and 40% were hyperechogenic. At the end of 6 months, they become either hyperechogenic or isoechogenic. The sonographic disappearance of saphenous vein in 90% of the limbs has been demonstrated after year. Partial or non occlusion of treated veins resulting in incomplete treatment

or subsequent recanalization is defined as the anatomical failure. Clinical improvement has been demonstrated in patients even with the anatomical failure. Symptom relief has been reported by several studies. There is Around 85% decrease in pain, edema or fatigue post operatively. There is low incidence of neovascularisation, is another advantage of RFA and is due to following reasons.

1. No incision and surgical dissection of groin,
2. Minimal hemodynamic disturbances because of preservation of physiological abdominal wall drainage.

A reflux free rate of 90% has been reported at 2 years and then 84% after 5 years. The next generation is the VNUS closure FAST catheter that was developed so as to improve the speed and ease of use as compared with current closure catheter.

OTHER USES OF RFA:

- ❖ RFA procedures are performed under image guidance by interventional radiologists and cardiologists of various procedures.
- ❖ To treat tumors like hepatocellular carcinoma, pancreatic Ca and bile duct cancers.

- ❖ Used in recurrent atrial flutter, atrial fibrillation, supraventricular tachycardia, atrial tachycardia and ventricular arrhythmias.
- ❖ RFA rhizotomy to treat severe chronic pain in lowback.
- ❖ It's a safe effective treatment for Barret's esophagus.
- ❖ Used in liver resections to control bleeding.

Materials & Methods:

It is a “Comparative study of Open surgery and Radio frequency ablation for varicose veins”.

Period of study:

May 2012- December 2013.

Place of study:

Department of general surgery and vascular surgery in Government Royapettah Hospital, Kilpauk Medical college Hospital.

Materials and Methods:

Pre operative & Post operative details will be collected from the inpatients admitted for open surgeries and Radio frequency ablation in above mentioned hospitals and data will be compared.

Focus will be on CEAP Classification, recurrence and residual disease, Number of days hospitalized, Pain scoring, Post operative bleeding, edema, infection.

Type of Study:

Comparative prospective study and interventional study.

Sample size:

30 patients in each category.

Inclusion Criteria:

1. Primary varicose veins with sapheno femoral incompetence.
2. CEAP grade 2 & 3 patients are selected.

Exclusion criteria:

1. Tortuous veins,
2. Secondary varicose veins,
3. Patients with Pacemakers,
4. Pregnancy,
5. Age more than 70 years,
6. Age less than 19 years,
7. Unmarried.

Conclusion:

By analyzing the various data available, the final result will be submitted.

RESULTS & OBSERVATION:**Statistical Analysis**

The results were tabulated on a spread sheet and statistical analysis was done using SPSS software with the help of bio-statistician.

Results

Improvement in CEAP class

Group	Parameter	At Presentation	At 3 months
Surgery	Mean	4.30	3.00
	Standard deviation	1.264	1.819
RFA	Mean	4.23	2.62
	Standard deviation	1.382	1.781

In the surgery group the mean CEAP class improved from 4.3 to 3.0. In the RFA group the mean CEAP class improved from 4.23 to 2.62. Using Mann-Whitney test, there was no statistically significant difference between the improvements seen in both the groups ($p=0.235$).

Improvement in Venous Severity Score (VSS):

Group	Parameter	At Presentation	At 3 months
Surgery	Mean	5.57	2.30
	Standard deviation	3.730	2.409
RFA	Mean	5.40	1.67
	Standard deviation	3.379	1.516

In the surgery group the mean VSS improved from 5.57 to 2.3. In the RFA group the mean VSS improved from 5.4 to 1.67. Using Mann- Whitney test, there was no statistically significant difference between the improvements seen in both the groups ($p=0.381$).

Symptomatic Improvement

In the surgery group 25 out of 30 patients i.e., 92.7% had symptomatic improvement compared to 28 out of 30 patients i.e., 98.3% in RFA group. There is no statistical difference in the symptomatic improvement between the two groups ($p=0.47$).

Complications

Surgery

Wound infection – 2

Wound dehiscence – 1

Bruising – 3

RADIO FREQUENCY ABLATION:

- Skin necrosis – 1

- Phlebitis – 1

- Staining – 1

Complications in both the groups were minor and rates were similar.

Analgesic requirements

Surgery:

– All patients required oral analgesics. In addition, 60% required injectable analgesic.

RFA

– Only 20% of patients in RFA required any analgesic.

Cost of procedure

- Surgery: Approximately, Rs.10,000.
- RFA: Approximately, Rs.5500

Time to return to work

- Surgery: Average 7 days
- RFA: Average < 1 day

Time required to do the procedure

Surgery: 45 – 70 min

RFA: 60 – 80 min.

NUMBER OF DAYS HOSPITALISED:

In surgery: average 7 days

In RFA: average 2 days

EVIDENCE OF POST OPERATIVE DVT:

No evidence of DVT IN surgery and RFA

RECURRENCE AT 3 MONTHS.

No evidence of recurrence in both groups.

DISCUSSION:

The idea behind both RFA and traditional vein stripping is that to remove the incompetent veins from the venous circulation so as to reduce the venous hypertension, with subsequent result in the resolution of symptoms but without significant morbidity. Postoperative pain reduction is markedly less in the RFA group than in the stripping groups, with the most significant differences between the 6th and 7th post operative period. The pain killers needed in the RFA group were less statistically. Medical leave were also significantly shorter in the RFA group. The restoration of physical activity is faster in the RFA group than the comparable group.

Venous severity score were nearly similar for both groups. Recurrence was not seen in both groups. But Lower pain score is seen in the RFA group verses the stripping group following the procedure.

The time required for surgery and RFA was almost the same.

Within 2 weeks, that is, the early follow up is focused on the comparison of the procedure related complications, patients recuperation, quality of life outcomes after the surgery and the procedure impact on the hemodynamic and clinical outcomes. No differences were observed between the groups in the patient demographics, VSS, CEAP, distribution both before and after treatment.

The most important differences seen between the two groups was on patients recovery. The mean time required for the patient to return to normal activities was 1.5 days for the RFA patient , compared to about 5 days that is required for venous stripping. The examination with Duplex ultra sound revealed 91.7% free of reflux in the RFA and 89.7% free of reflux in the vein stripping surgery.

Both the RFA and venous stripping methods were successful and the complications were nearly similar between the groups in the study as it was with the other studies conducted. Important differences was seen in the patients recovery and in the return to work. And the most important point is that, RFA is the treatment of choice for recurrence saphenous vein reflux.

PICTURES



Varicose vein – Long saphenous vein



Flush ligation of saphenofemoral junction





Ligation of distal end of saphenous vein



Mayo's Stripping.

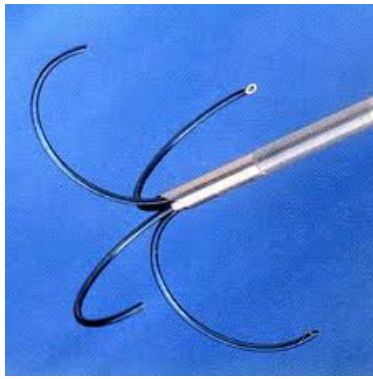


Subfacial ligation of perforator



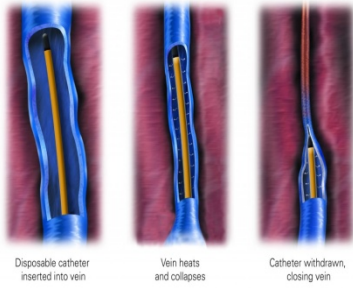


Radio frequency Ablation of veins UNIT

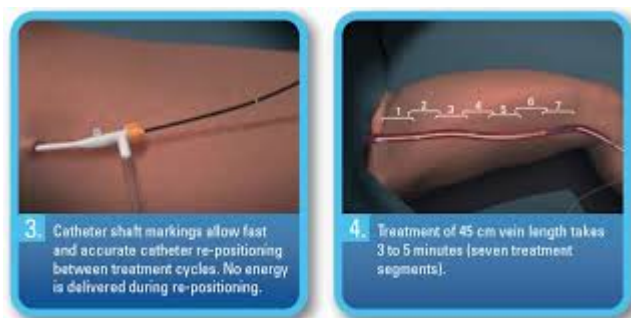
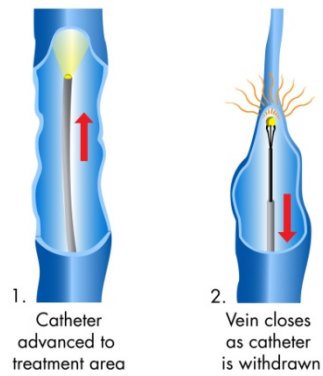
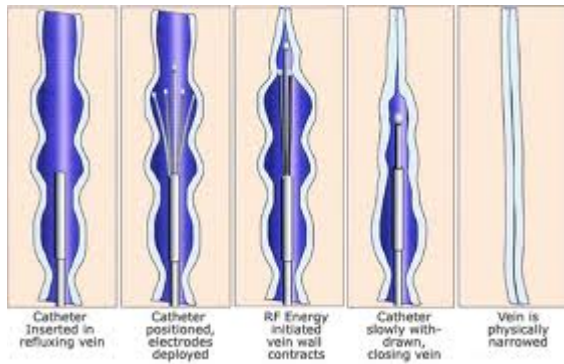


Closure catheters





Mechanism of action of RFA



Effect of RFA - Graphs

Mean Venous Severity Score at presentation and 3 months

Mean Venous Severity Score

Figure 1 Venus severity score at end of three months

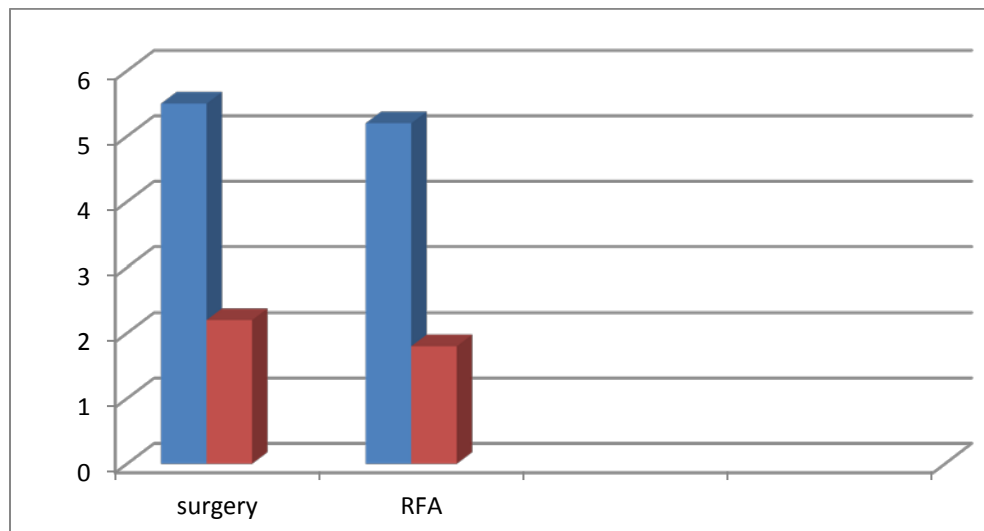
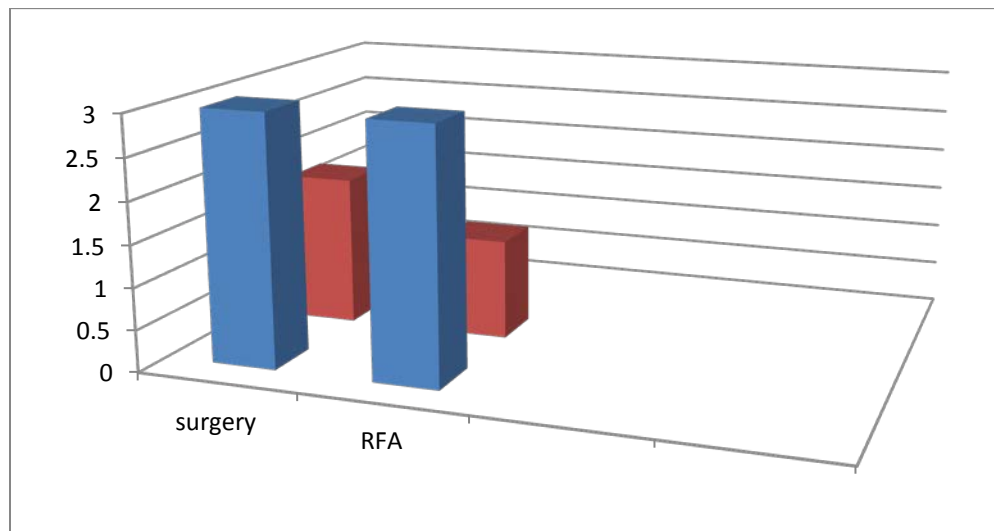


Figure 2 Mean CEAP after surgery



Conclusion:

The favoured alternative choice in the treatment of superficial and perforator venous reflux disease in the newer era is the endovenous radio frequency ablation. The RFA not only out performs the traditional vein stripping and perforator interruption with regard to morbidity and outcome, it also reduces the formation of neovascularization that is frequently blamed reason for the higher recurrence rates seen with vein stripping.

Obliteration of superficial venous system in short term (3 months) is similar in surgery and RFA. Clinical improvement as measured CEAP class and venous severity score are similar in both groups. Complications in both the groups are minor and relatively less frequent. RFA is less morbid than surgery. Patients undergoing RFA returned to work earlier. Cost effectiveness is significantly similar in both groups. Post operative pain is significantly less in RFA than in surgery.

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Masterchart:

MASTER CHART

SEG – segment

1 – Right long saphenous vein

2 – Left long saphenous vein

SUR/RFA

SUR – surgery – 1

RFA – Radio frequency ablation – 2

BLEED

0 – No bleed

1 – Mild to moderate

2 – Severe

INFECTION

0 – No infection

1 – Infection present

PAIN

0 – No Pain

1 – Mild to moderate

2 – Severe.

DVT – Deep Vein Thrombosis

0 – No DVT

1 – DVT present

AMBULANCY

1 – Ambulant within 2 days

2 – Ambulant within 5 days

EDEMA:

0 – No edema, 1 – Edema present.

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ANNEXURE

EVALUATION FORM

Name :

Age :

Sex :

IP No :

Occupation :

Date of Admission :

Date of Surgery :

Date of discharge :

Chief Complaints :

General Examination:

Local Examination :

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Investigations :

Operative management:

CEAP Classificaton:

Pre – OP :

Post – OP :

Number of days hospitalized:

Post Operative

Bleeding :

Limb Edema :

Infection :

Saphenous Neuralgia:

Residual Disease :

Pain scoring :

Recurrence :

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CEAP CLASSIFICATION FORM

Clinical		At presentation		After 3 months	
		Right	Left	Right	Left
No visible signs	0				
Telangiectasia or reticular veins	1				
Varicose veins	2				
Edema	3				
Skin changes	4				
Skin changes with healed ulcer	5				
Skin changes with active ulcer	6				

Clinical score	At presentation		After 3 months	
	Right	Left	Right	Left
PAIN				
None0				
Moderate No analgesia1				
Severe No analgesia2				
EDEMA				
None0				
Mild to Moderate1				
Severe2				
VENOUS CLAUDICATION				
None0				
Mild to Moderate1				
Severe2				
PIGMENTATION				
None0				
Localised1				
Extensive2				

LIPODERMATOSCLEROSIS					
None	0				
Localised	1				
Extensive	2				
ULCER					
None	0				
Present	1				
Recurrence	2				

சுய ஒப்புதல் படிவம்

Comparative study of Open surgery and Radio frequency ablation for varicose veins.

ஆராய்ச்சி நிலையம் : பொது அறுவை சிகிச்சை துறை
கீழ்ப்பாக்கம், மருத்துவக் கல்லூரி
சென்னை - 600 010.

பங்கு பெறுபவரின் பெயர் : வயது :

பங்கு பெறுபவரின் எண். :

பங்கு பெறுபவரது இதனை (✓) குறிக்கவும்

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும், அதற்கான தகுந்த விளக்கங்களைப் பெறவும் வாய்ப்பளிக்கப்பட்டது.

நான் இவ்வாய்வில் தன்னிச்சையாகத்தான் பங்கேற்கிறேன். எந்தக் காரணத்தினாலோ எந்தக் கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகிக் கொள்ளலாம் என்று அறிந்து கொண்டேன்.

இந்த ஆய்வு சம்மந்தமாகவோ, இதைச் சார்ந்த மேலும் ஆய்வு மேற்கொள்ளும்போது இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளைப் பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். நான் ஆய்வில் இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன்.

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான முடிவுகளையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக் கொள்ளவும் அதைப் பிரசுரிக்கவும் என் முழு மனதுடன் சம்மதிக்கிறேன்.

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன். எனக்குக் கூறப்பட்ட அறிவுரைகளின்படி நடந்து கொள்வதுடன், இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்றும் உறுதியளிக்கிறேன். என் உடல் நலம் பாதிக்கப்பட்டாலோ அல்லது எதிர்பாராத நோய்க்குறி தென்பட்டாலோ உடனே அதை மருத்துவ அணியிடம் தெரிவிப்பேன் என உறுதி அளிக்கிறேன்.

பங்கேற்பவரின் கையொப்பம்..... இடம்..... தேதி
கட்டைவிரல் ரேகை

பங்கேற்பவரின் பெயர் மற்றும் விலாசம்.....

ஆய்வாளரின் கையொப்பம்..... இடம்..... தேதி

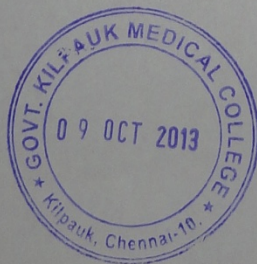
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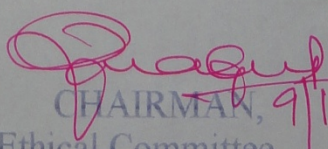
INSTITUTIONAL ETHICAL COMMITTEE
GOVT.KILPAUK MEDICAL COLLEGE,
CHENNAI-10
Ref.No.3393/ME-1/Ethics/2013 Dt:02.05.2013
CERTIFICATE OF APPROVAL

The Institutional Ethical Committee of Govt. Kilpauk Medical College, Chennai reviewed and discussed the application for approval "A Study of comparative study of open surgery and radio frequency ablation for varicose veins" – For doing Research Work submitted by Dr.G.Kavithal,MS (GS), PG Student, KMC, Chennai-10.

The Proposal is APPROVED.

The Institutional Ethical Committee expects to be informed about the progress of the study any Adverse Drug Reaction Occurring in the Course of the study any change in the protocol and patient information /informed consent and asks to be provided a copy of the final report.




CHAIRMAN, 9/10/13.
Ethical Committee
Govt. Kilpauk Medical College,
Chennai
